EXHIBIT 167

QUALITEST/VINTAGE
7289-001

U.S. Department of Justice

Alice H. Martin
United States Attorney
Northern District of Alabama

Lloyd C. Peeples, AUSA
Deputy Chief, Civil Division
205-244-2116
lloyd.peeples@usdoj.gov

Civil Division
1801 Fourth Avenue North
Birmingham, AL 35203-2101

(205) 244-2001
FAX (205) 244-2181

September 27, 2010

Robert Mills
President
Vintage Pharmaceuticals, LLC
150 Vintage Drive
Huntsville, AL 35811

In re: Violations of the Controlled Substances Act

Dear Mr. Mills:

Our office is currently investigating allegations under the Controlled Substances Act, 21 U.S.C. § 801, et seq. Specifically, the allegations currently under investigation concern record-keeping requirements prescribed by federal law.

We would like to set a time to discuss these matters and listen to anything you would like us to consider. If you wish to take advantage of this opportunity, please contact me by October 8, 2010. I look forward to hearing from you soon.

Sincerely,

JOYCE WHITE VANCE
UNITED STATES ATTORNEY

LLOYD C. PEEPLES, III
Assistant United States Attorney

cc: Gale B. Jones, DI, DEA

JOHN GILBERT
202-737-4293
CELL 703-304-8673
JGILBERT@HPM.COM

Department of Justice
Drug Enforcement Administration

FAX Transmittal Sheet for UNCLASSIFIED Information Only

1 10 / 06 / 2010
Transmission Date (MM/DD/YYYY)

2 Number of pages being transmitted (including this transmittal sheet) 4

3 TO:
FAX FTS #: 256-859-4021
FAX COMMERCIAL #:
NAME: John Schultz
Qualitest
PHONE:
OFFICE/ORG.

4 FROM:
FAX FTS #:
FAX COMMERCIAL #:
NAME: Patricia Millier, Group Supervisor
DEA
PHONE: 205-321-8601
OFFICE/ORG:

5 Additional Comments

Per our conversation.

"NOTICE: This is an official government communication that may contain privileged or sensitive information intended solely for the individual or entity to which it is addressed. Any review, retransmission, dissemination, or other use or action taken upon this information by persons or entities other than the intended recipient is prohibited. If you are not the intended recipient or believe you received this communication in error, please contact the sender immediately."

Note: If you have any problems with this transmission (incorrect number of pages/poor quality), call the sender and request retransmission

DEA Form 501 Fax Transmittal Sheet for Unclassified Information Only
(September 2008)

VIOLATIONS:

1. VINTAGE PHARMACEUTICALS, LLC failed to take an initial inventory, in violation of 21 CFR 1304.11(b). VINTAGE was required to take an initial inventory of all stocks of controlled substances on hand on the date VINTAGE first engages.

Law: 21 USC 827(a)(1).

Regulation: 21 CFR 1304.11(b).

Violation: 21 USC 842(a)(5).

Penalty: $10,000.00.

Redacted - Privileged Material

2. VINTAGE PHARMACEUTICALS, LLC failed to take a biennial inventory, in violation of 21 CFR 1304.11(c).

Law: 21 USC 827(a)(1).

Regulation: 21 CFR 1304.11(c).

Violation: 21 USC 842(a)(5).

Penalty: $10,000.00.

Redacted - Privileged Material

3. VINTAGE PHARMACEUTICALS, LLC failed to create an inventory list: a. The name of the substance; and b. The total quantity of the substance to the nearest metric unit. In violation of 21 CFR 1304.11(e)(4).

Law: 21 USC 827(b)(1).

Regulation: 21 CFR 1304.11(e)(1)(i).

Violation: 21 USC 842(a)(5).

Penalty: $10,000.00.

Redacted - Privileged Material

4. VINTAGE PHARMACEUTICALS, LLC completed an application with the Import/Export Unit, Drug Enforcement Administration (DEA), to import a Schedule II controlled substance, in violation of 21 CFR 1312.11(a), and 21 CFR 1312.12(a). VINTAGE PHARMACEUTICALS, LLC, DEA #RV0359439 was registered with DEA on November 8, 2007 in as an Importer of controlled substances in Schedules IIIN and IV.

Law: 21 USC 952(a).

Regulation: 21 CFR 1312.11(a).

: 21 CFR 1312.12(a).

Violation: 21 USC 960(a)(1).

: 21 USC 842(b)(1).

Penalty: 21 USC 960(b).

: $25,000.

Redacted - Privileged Material

5. VINTAGE PHARMACEUTICALS, LLC failed to return permit #5914 for cancellation, to the Import/Export Unit, of Drug Enforcement Administration six months following the issue date of April 2, 2008, with an expiration date of October 2, 2008, in violation of 21 CFR 1312.16(b).

Law: 21 USC 952(a).

: 21 USC 823(d)(1)

Regulation: 21 CFR 1312.16(b).

Violation: 21 USC 960(a)(1).

Penalty: 21 USC 960(b).

Redacted - Privileged Material

6. VINTAGE PHARMACEUTICALS, LLC failed to return in process, controlled substances (bulk material) to the Importer designated controlled substance storage area, located within the Schedule II controlled substance vault, in violation of 21 CFR 1301.73(a). It was noted that controlled substance (bulk material) was left in the Schedule III through V controlled substance cage area after the termination of manufacturing process.

Law: 21 USC 823(d)(5).

Regulation: 21 CFR 1301.73(a).

Violation: 21 USC 960(a)(1).

Penalty: 21 USC 960(b).

: 21 USC 842(c)(2)(A) $25,000.00.

7. VINTAGE failed to record the name, address, and registration number of VINTAGE PHARMACEUTICALS, LLC, Manufacturer, DEA #RV0359299, when the bulk controlled substances was distributed for manufacturing, in violation of 21 CFR 1304.22(a)(2)(i)(iv)(v) and (vii).

Law: 21 USC 827(a)(3); 827 (b)(1).

Regulation: 21 CFR 1304.22(a)(2)(i)(iv)(v), and 1304.22(d).

Violation: 21 USC 842(a)(5).

Penalty: $10,000.00.

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

JOHN A. GILBERT, JR.

Direct Dial (202) 737-4293

7289.001.01

October 12, 2010

VIA EMAIL AND FACSIMILE

Lloyd C. Peeples
Assistant United States Attorney
Deputy Chief Civil Division
U.S. Department of Justice
Northern District of Alabama
1801 Fourth Avenue North
Birmingham, Alabama 35203-2101

RE: Vintage Pharmaceuticals, LLC

FOR SETTLEMENT DISCUSSIONS ONLY
PURSUANT TO FRE 408

Dear AUSA Peeples:

The purpose of this letter is to follow-up on our recent telephone conference of Friday, October 9, 2010 concerning your letter to Vintage Pharmaceuticals, LLC ("Vintage") dated September 27, 2010. We are also in receipt of the information provided by the DEA Field Office regarding specific alleged violations of the Controlled Substances Act ("CSA") and applicable regulations. As discussed, we would welcome the opportunity to meet with you at your earliest convenience to discuss these matters. To that end, I thought it would be helpful in preparation for any future meeting to provide you with the following: (1) background information concerning Vintage; (2) an explanation of the substantive issues raised by the local DEA office; and, (3) a summary of why Vintage believes that a civil penalty is unnecessary.

Background Concerning Vintage/Qualitest

Headquartered in Huntsville, Alabama, Generics International (U.S.), Inc., dba Qualitest Pharmaceuticals ("Qualitest") is the sixth largest generic pharmaceutical company in the United States, based on number of generic prescriptions filled, and currently has

approximately 1,200 employees. The Company has the following subsidiaries: (1) Generics Bidco I, LLC, the company headquarters and distribution facilities in Huntsville; (2) Vintage Pharmaceuticals, LLC, which consists of the two manufacturing plants located in Huntsville, one for tablet drugs and one for liquid drugs; and, (3) Generics Bidco II, LLC, which represents the operations of the manufacturing plant in Charlotte, North Carolina.

Qualitest/Vintage holds seven separate DEA registrations for these facilities, including the following: Qualitest (distributor) [redacted] Qualitest (exporter) [redacted] Vintage Charlotte (manufacturing) [redacted] Vintage Liquids-Huntsville (manufacturing) [redacted] Vintage Tablets–Huntsville (manufacturing) [redacted] Vintage Tablets (importer) [redacted] and Vintage tablets (analytical lab) [redacted] The Qualitest/Vintage facilities annually manufacture and distribute a combined 612 different products totaling 70,391,797 units sold, of which 20,799,585 are controlled substances.

The DEA approved Qualitest/Vintage's first manufacturing registration in 1992. To date, Qualitest/Vintage has had an exceptional record of compliance concerning all aspects of the CSA and its implementing regulations. In its eighteen years of operation, Qualitest/Vintage has received only two DEA letters of admonition – one in 1993 under a previous DEA manufacturer's registration at the Vintage Charlotte plant, and one as a result of the recent inspection at the Qualitest Distribution Center. Both of these letters of admonition are unrelated to its importer registration, and both raised minor concerns that Qualitest/Vintage immediately corrected. Qualitest/Vintage has an exceptional history of compliance with the CSA, and with DEA requests of any nature whatsoever. Qualitest/Vintage is committed to continued cooperation with the DEA.

Specific Responses To Allegations Raised by DEA

Below is a summary response to the allegations set forth in the fax received from DEA resulting from the DEA Birmingham District Office's August 2-5, 2010 inspection of the importer registration at the Vintage Tablets-Huntsville facility.

As a preliminary matter, the allegations relate primarily to the importer registration at Vintage Tablets-Huntsville and the isolated case of the importation of Alprazolam, which is a Schedule IV active pharmaceutical ingredient ("API"), and Vintage's inadvertent failure to return an expired DEA import permit. The allegations derive from the fact that the receipt of Alprazolam at the Huntsville facility was recorded in the manufacturing log instead of the import log. It was then stored in the designated Schedule C IV controlled substances area, and not the designated import area within the controlled substances vault.

Vintage promptly corrected this inadvertent oversight upon DEA's notification of this issue during the inspection.

With respect to the specific allegations, each of which derive generally from this inadvertent co-mingling between the importer and manufacturer registrations, Vintage responds as follows:

ALLEGATION NO. 1

1. *VINTAGE PHARMACEUTICALS, LLC failed to take an initial inventory, in violation of 21 CFR 1304.11 (b). VINTAGE was required to take an initial inventory of all stocks of controlled substances on hand on the date VINTAGE engages.*

VINTAGE RESPONSE:

Vintage in fact did take an initial inventory of all stocks of controlled substances on hand on the date Vintage first engaged in controlled substance manufacturing and distributing under the manufacturing, distribution and analytical lab registrations, in accordance with 21 C.F.R. § 1304.11(b). There was no inventory of imported controlled substances on hand at that time to conduct an inventory; however, Vintage did not record a "0" inventory under the import registration. Vintage will take steps to ensure that it records "0" inventories in the future as appropriate.

ALLEGATION NO. 2

2. *VINTAGE PHARMACUETICALS, LLC failed to take a biennial inventory, in violation of 21 CFR 1304.11 (c).*

VINTAGE RESPONSE:

Vintage did take a biennial inventory of stocks of controlled substances as required for the manufacturing, distribution and analytical lab registrations. However, there was no inventory of imported controlled substances on hand at the time of the biennial inventory. As in Allegation No. 1, Vintage did not record a "0" inventory. Vintage has since taken a biennial inventory of imported controlled substances on hand and recorded it as "0". Vintage will take steps to ensure that it continues to record "0" inventories in the future as appropriate.

ALLEGATION NO. 3

3. *VINTAGE PHARMACEUTICALS, LLC failed to create an inventory list: a. The name of the substance; and b. The total quantity of the substance to the nearest metric unit. In violation of 21 CFR 1304.11 (e) (4).*

VINTAGE RESPONSE:

Vintage did create inventory lists, which included the name of the substance, and the total quantity of the substance to the nearest metric unit for the manufacturing, analytical lab and distribution registrations. There was no inventory (i.e., the inventory was "0") of controlled substances for the importer registration; therefore, Vintage did not fail to identify the "name of the substance" or "the quantity" because there was, in fact, none with respect to that registration.

ALLEGATION NO. 4

4. *VINTAGE PHARMACEUTICALS, LLC completed an application with the Import/Export Unit, Drug Enforcement Administration (DEA), to import a Schedule II controlled substance, in violation of 21 CFR 1312.11 (a), and 21 CFR 1312.12 (a). VINTAGE PHARMACEUTICALS, LLC* [redacted] *was registered with DEA on November 8, 2007 in [sic] as an Importer of controlled substances in Schedules IIIN and IV.*

VINTAGE RESPONSE:

Vintage completed and submitted an import permit application to the Import/Export Unit at DEA for the import of a Schedule II Research and Development reference listed drug sample, which was for a total of 336 capsules of Medikenet XL (Methylphenidate HCl capsules), which was to be used in the development of the generic product. The Import/Export Unit at DEA received and reviewed Vintage's import permit application, and issued Vintage import permit No. 5914 for permission to import these Schedule II samples. Vintage never imported these samples, and, notably, Vintage did not import or cause to be imported any other Schedule II drug for which it was not registered with DEA.

ALLEGATION NO. 5

5. *VINTAGE PHARMACEUTICALS, LLC failed to return permit #5914 for cancellation, to the Import/Export Unit, of Drug Enforcement Administration six months following the issue date of April 2, 2008, with an expiration date of October 2, 2008, in violation of 21 CFR 1312.16 (b).*

VINTAGE RESPONSE:

The unused import permit referenced in Allegation No. 5 above (No. 5914), expired after six months. Vintage was aware of the expiration of the unused permit but was unaware of the requirement to return the expired permit to DEA for cancellation after its expiration, because Vintage was unaware that an "expired" permit required the additional step of "cancellation." Vintage's alleged failure to return the import permit after the expiration period was, at most, an inadvertent, honest mistake.

ALLEGATION NO. 6:

6. *VINTAGE PHARMACEUTICALS, LLC failed to return in process, controlled substances (bulk material) to the Importer designated controlled substance storage area, located within Schedule II controlled substance vault, in violation of 21 CFR 1301.73 (a). It was noted that controlled substance (bulk material) was left in the Schedule III through V controlled substance cage area after the termination of manufacturing process.*

VINTAGE RESPONSE:

The in process, controlled substance material is part of the Vintage's DEA manufacturing registration during the manufacturing process. The in process material was returned to the appropriate storage area for Schedule IV materials which is the Schedule III – Schedule V cage during the manufacturing process. Had the imported Alprazolam material been received into the import log and stored in the designated import area it would have been transferred to the manufacturing registration prior to the start of the manufacturing process and stored in the Schedule

III – Schedule V manufacturing cage as required. When Vintage became aware as a result of the DEA inspection of this gap in the appropriate receipt and handling of imported controlled substances, it immediately took corrective action, including the development and implementation of a new standard operating procedure, titled "Vintage SOP - Comp 51006 - The Purchase, Receipt, Storage and Handling of Imported Controlled Substances." This SOP was written and implemented promptly after the DEA completed its inspection and before the importation of any additional controlled substance materials to the facility. All relevant employees have received training on the appropriate handling of imported controlled substances as required by the new SOP.

ALLEGATION NO. 7

7. *VINTAGE failed to record the name, address, and registration number of VINTAGE PHARMACEUTICALS, LLC, Manufacturer, [redacted] when the bulk controlled substances was* [sic] *distributed for manufacturing, in violation of 21 CFR 1304.22(a) (2) (i) (iv) (v) and (vii).*

VINTAGE RESPONSE:

Vintage routinely records the name, address and registration number each time it makes a transfer of controlled substances from one registration to another registration. The Alprazolam, when received, was not received into the importer registration; therefore, it was not transferred to the manufacturer's registration but, instead, originally received in the manufacturer's registration. Vintage now understands that the Alprazolam product should have been received (and thus recorded) under the importer registration, and then transferred (and thus recorded) to the manufacturer's registration at the time of manufacturing. As described in Response to Allegation No. 6 above, upon being advised of the record keeping discrepancy, Vintage promptly implemented the new SOP and trained all relevant employees in the appropriate handling and record keeping of controlled substances pursuant to multiple registrations.

An Assessment of Civil Penalties Based on DEA's Alleged Violations is Not Warranted and Unnecessary

DEA's alleged violations involve various recordkeeping and reporting violations, all of which have been corrected. These allegations are isolated instances and not cases where Vintage failed to correct known deficiencies. There are also no allegations that these violations resulted in diversion or in any way affected the safe storage and distribution of controlled substances. Thus, such allegations, even if true, would normally be handled through a letter of admonition or a memorandum of agreement.

A review of the legislative history of the Controlled Substances Civil Penalty Reform Act confirms that Congress did not contemplate a payment of civil penalties for these types of minor violations. The CSA civil penalty amendments in 1998 were intended to direct DEA to follow a course of judicious review and to prevent the assessment of exorbitant civil penalties. Greg Williams, DEA's Chief of Operations at the time, testified that it is "DEA's policy that only those cases that reveal criminal activity, substantial shortages of controlled substances, or egregious disregard for regulatory obligations will be referred for civil action or criminal prosecution." Drug Diversion Investigations Before the Subcommittee on Crime of the House Judiciary Committee, 106th Cong. 6 (1998) (testimony of Greg Williams, Chief of Operations, DEA). Vintage's cited conduct consists of now-rectified honest mistakes or minor (in fact, technical) violations of the CSA, not criminal activity or any egregious disregard for either its regulatory or statutory obligations.

Similarly, the House Report accompanying the passage of the Controlled Substances Civil Penalty Reform Act lists certain factors that DEA must consider when deciding to pursue civil fines for certain recordkeeping and reporting violations:

1. Whether the diversion actually occurred;
2. Whether harm to the public occurred;
3. Whether the violations were intentional or negligent in nature;
4. Whether the violations were a first time offense;
5. The time intervals between inspections without serious violations;
6. Whether the violations were multiple occurrences of the same type of violation;
7. Whether and to what extent financial profits may have resulted from the illegal activity; and,
8. The financial capacity of the registrant to pay.

Consideration of these factors plainly demonstrates that a civil fine is unwarranted here. Vintage's first-time, harmless record keeping issues were at worst negligence, but

more likely honest mistakes for which it took immediate, appropriate corrective action after the DEA inspection. Neither harm to the public nor diversion of controlled substances was threatened or occurred. Not only are the alleged violations first time offenses, but Vintage also has an exceptional history of compliance with DEA recordkeeping and other requirements. All of the alleged violations arose out of the same type of violation, i.e., the proper storage and transfer of a controlled substance vis-à-vis two separate registrations – importation and manufacturing, and the minor issue of returning an expired import permit. Lastly, although, Vintage does not deny that it may have the financial ability to pay a fine, it derived no financial profits from the alleged wrongful activity.

For all of these reasons, imposition of a civil fine is simply an unnecessary sanction that would be of little remedial value. An appropriate remedial action could take the form of a letter of admonition or a memorandum of understanding memorializing past and future corrective action and cooperation taken by Vintage.

Conclusion

Vintage looks forward to meeting with you at your earliest available opportunity to discuss the allegations and address any questions or concerns you may have. Vintage also believes that with an open and continuing dialogue, the parties can work towards a mutually beneficial resolution of the issues raised in DEA's communication on the alleged violations.

Sincerely,

John A. Gilbert

cc: Patricia Millier, Group Supervisor, DEA
Gale Jones, DI, DEA

Jaime Poliansky 7289.001.01

From: Karla L. Palmer
Sent: Wednesday, February 16, 2011 3:56 PM
To: Blake Cullen (rmills@qualitestrx.com)
Cc: John A. Gilbert
Subject: FW: Vintage Pharmaceuticals --- signed MOA
Attachments: Vintage Executed Settlement Agreement.pdf

Blake, attached is the signed DEA settlement agreement. Since all parties have signed, please pay the amount of $15,000 per the directions set forth in paragraph 1 of the agreement, within thirty days of yesterdays' date.

I have reprinted the payment paragraph here, for ease of reference for you:

1. Vintage agrees to pay the United States the amount of fifteen thousand dollars ($15,000.00). Payment shall be made by check payable to the United States Department of Justice, and delivered to the United States Attorney for the Northern District of Alabama, 1801 4th Avenue North, Birmingham, AL 35203. The total amount will be paid no later than thirty days from the Effective Date of this Agreement.

Please let us know when you have paid, for our records, and if you have any questions.

Thanks much for taking care of this.

Regards,

Karla L. Palmer
Hyman, Phelps & McNamara, P.C.
700 13th Street NW
Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-7542 (direct)
(202) 737-9329 (fax)

kpalmer@hpm.com

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2/16/2011

From: Peeples, Lloyd (USAALN) [mailto:Lloyd.Peeples@usdoj.gov]
Sent: Tuesday, February 15, 2011 11:42 PM
To: Karla L. Palmer
Cc: John A. Gilbert
Subject: RE: Vintage Pharmaceuticals --- draft MOA

Attached is the executed settlement agreement.

From: Karla L. Palmer [mailto:KPalmer@hpm.com]
Sent: Tuesday, February 15, 2011 9:22 AM
To: Peeples, Lloyd (USAALN)
Cc: John A. Gilbert
Subject: RE: Vintage Pharmaceuticals --- draft MOA

Lloyd, attached is the revised page 5 for your signature. Please let me know if you need anything else.

Regards,

Karla L. Palmer
Hyman, Phelps & McNamara, P.C.
700 13th Street NW
Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-7542 (direct)
(202) 737-9329 (fax)

kpalmer@hpm.com

Visit the HPM blog: www.fdalawblog.net <http://www.fdalawblog.net/>

From: Peeples, Lloyd (USAALN) [mailto:Lloyd.Peeples@usdoj.gov]
Sent: Tuesday, February 15, 2011 7:35 AM
To: Karla L. Palmer
Cc: John A. Gilbert
Subject: Re: Vintage Pharmaceuticals --- draft MOA

You can just email the revised page and I can attach it.

From: Karla L. Palmer [mailto:KPalmer@hpm.com]
Sent: Tuesday, February 15, 2011 06:53 AM

To: Peeples, Lloyd (USAALN)
Cc: John A. Gilbert <JGilbert@hpm.com>
Subject: RE: Vintage Pharmaceuticals --- draft MOA

Thanks. We will resend.

Regards,

Karla

-----Original Message-----
From: Peeples, Lloyd (USAALN) [mailto:Lloyd.Peeples@usdoj.gov]
Sent: Mon 2/14/2011 10:51 PM
To: Karla L. Palmer
Cc: John A. Gilbert
Subject: RE: Vintage Pharmaceuticals --- draft MOA

I received the executed agreement in the mail. The signature page for my office includes signature lines for both the US Attorney and myself. Typically, the US Attorney does not personally sign these documents. The usual signature block looks like this:

JOYCE WHITE VANCE

UNITED STATES ATTORNEY

_____

LLOYD C. PEEPLES, III

Assistant United States Attorney

1801 4th Avenue North

Birmingham, AL 35203

Telephone: (205) 244-2116

Counsel for United States

If this is acceptable, please resend me a revised signature page for me to execute and send back to you.

From: Karla L. Palmer [mailto:KPalmer@hpm.com]
Sent: Friday, January 28, 2011 9:52 AM
To: Peeples, Lloyd (USAALN)

Cc: John A. Gilbert
Subject: RE: Vintage Pharmaceuticals --- draft MOA

Thanks so much. We will accept the changes, and start the signature process.

Have a great weekend.

Best regards,

Karla

Karla L. Palmer
Hyman, Phelps & McNamara, P.C.
700 13th Street NW
Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-7542 (direct)
(202) 737-9329 (fax)

kpalmer@hpm.com

Visit the HPM blog: www.fdalawblog.net <http://www.fdalawblog.net/>

From: Peeples, Lloyd (USAALN) [mailto:Lloyd.Peeples@usdoj.gov]
Sent: Thursday, January 27, 2011 10:07 PM
To: Karla L. Palmer
Cc: John A. Gilbert
Subject: RE: Vintage Pharmaceuticals --- draft MOA

The proposed changes are acceptable. If you want to go ahead and get the agreement signed and then send it to me, I will execute it and send back a scanned final version.

From: Karla L. Palmer [mailto:KPalmer@hpm.com]
Sent: Thursday, January 27, 2011 11:20 AM
To: Peeples, Lloyd (USAALN)
Cc: John A. Gilbert
Subject: Vintage Pharmaceuticals --- draft MOA

Dear Lloyd:

I work with John Gilbert at Hyman Phelps & McNamara. We have reviewed the draft MOA that you sent to us and have attach a redlined version. Please contact us with any additional comments or suggestions that you may have. We look forward to discussing this with you.

Best regards,

Karla L. Palmer
Hyman, Phelps & McNamara, P.C.
700 13th Street NW
Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-7542 (direct)
(202) 737-9329 (fax)

kpalmer@hpm.com

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<http://www.fdalawblog.net/>

<<Vintage Settlement Agreement 1.27.docx>>

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into between the United States Attorney for the Northern District of Alabama, acting on behalf of the United States of America, and Vintage Pharmaceuticals, LLC ("Vintage"), a facility registered with the Drug Enforcement Administration ("DEA") at the time the events described herein occurred. This Agreement is in settlement of certain allegations made by the DEA against Vintage, wherein it is alleged Vintage failed to maintain complete and accurate records and inventories of controlled substances imported and/or received in violation of federal statute and regulations, the details of which are more fully set out below.

RECITALS

A. In 2010, Vintage was registered as an importer of Schedule III and IV controlled substances with the DEA. The Controlled Substances Act, ("CSA"), 21 U.S.C. § 801, et seq., and regulations promulgated thereunder, 21 C.F.R. § 1300, et seq., establish record-keeping requirements, which apply to pharmaceutical importers who order, receive, and maintain quantities of controlled substances from a manufacturer. See 21 U.S.C. § 827(a)(1) and 21 C.F.R. §§ 1304.11(a), (b) and (c).

B. Beginning on August 2, 2010, and ending on August 5, 2010, the DEA conducted a Scheduled Regulatory Investigation ("SRI") of Vintage for the time period February 2, 2010 through August 2, 2010. During its investigation, the DEA found that Vintage allegedly violated the above-cited record-keeping regulations. The DEA contends that the violations include:

(i) Vintage's failure to take an initial inventory of Alprazolam, a Schedule IV controlled substance, on the date it was received; and,

(ii) Vintage's failure to take a biennial inventory of any and all imported controlled substances.

C. Both the United States and Vintage now desire to reach a full and final civil monetary settlement concerning the specific allegations set forth above.

D. This Agreement is neither an admission of liability by Vintage nor a concession by the United States that its claims are not well founded. Nevertheless, to avoid the delay, expense, inconvenience and uncertainty of litigation of these claims, the Parties have reached a full and final settlement pursuant to the Terms and Conditions set forth below.

TERMS AND CONDITIONS OF AGREEMENT

In consideration of the mutual obligations set forth below, the sufficiency of which is hereby acknowledged, and intending to be legally bound thereby, the United States and Vintage agree as follows:

1. Vintage agrees to pay the United States the amount of fifteen thousand dollars ($15,000.00). Payment shall be made by check payable to the United States Department of Justice, and delivered to the United States Attorney for the Northern District of Alabama, 1801 4th Avenue North, Birmingham, AL 35203. The total amount will be paid no later than thirty days from the Effective Date of this Agreement.

2. The United States agrees that, conditioned upon Vintage's compliance with paragraph 1 above, it shall release Vintage from any and all civil liability related to the allegations described herein and arising from the SRI.

3. Both the United States and Vintage agree that, in the event Vintage does not comply with the provisions of paragraph 1 above, the United States may declare this Agreement void and may proceed with an action in the United States District Court for the Northern District of Alabama against Vintage for whatever civil monetary penalties the United States may be entitled to recover.

4. This Agreement does not release Vintage or any other entity or individual from any administrative actions or decisions regarding licensing, registration, suspension, debarment, or exclusion.

5. This Agreement does not release any individual or entity from any criminal liability.

6. The parties acknowledge that there is no finding or admission of liability that may result in the exclusion from participation in any Federal health care program.

7. This Agreement does not release any entity or individual from any claims arising under Title 26 of the U.S. Code (Internal Revenue Code).

8. Vintage represents that it has had, and has relied upon, the advice of its own counsel in connection with this Agreement and that the terms of the Agreement are fully understood and voluntarily accepted by Vintage.

9. This Agreement constitutes the complete agreement between the Parties.

10. This Agreement may be executed in counterparts, each of which constitutes an original and all of which shall constitute one and the same agreement.

11. This Agreement may not be amended except by written consent of the Parties.

12. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date").

13. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

Entered into this _____ day of ~~January~~ February, 2011

VINTAGE PHARMACEUTICALS, LLC

By: Daniel J Cadow

Title: Sr VP Generics Business Unit

Date: 2/6/11

ENDO LEGAL

JOYCE WHITE VANCE
UNITED STATES ATTORNEY

LLOYD C. PEEPLES, III
Assistant United States Attorney
1801 4th Avenue North
Birmingham, AL 35203
Telephone: (205) 244-2116

Counsel for United States

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